

An educational primer intended to promote compliance

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Environment and Climate Change Canada / Health Canada Significant New Activity (SNAc) Pro	ovisions
U.S. Environmental Protection Agency Significant New Use Rule (SNUR) Programs and	

U.S. Environmental Protection Agency Significant New Use Rule (SNUR) Programs and Environment and Climate Change Canada / Health Canada Significant New Activity (SNAc) Provisions
This primer provides information and example scenarios meant to serve as an easy-to-follow resource for understanding Significant New Use Rule (SNUR) and Significant New Activity (SNAc) compliance. The primary goal of this document is to promote compliance among the regulated community. This document does not substitute for any SNUR or SNAc provisions, nor is it a rule itself. It does not impose legally binding requirements on the regulated community or on the U.S. Environmental Protection
Agency, Environment and Climate Change Canada, or Health Canada.
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Acronym Listing

CCPSA Canada Consumer Product Safety Act

CDX Central Data eXchange (U.S.)

CEPA Canadian Environmental Protection Act

DSL Domestic Substances List (Canada)

ECCC Environment and Climate Change Canada

EPA U.S. Environmental Protection Agency

HC Health Canada

HCS Hazard Communications Standards (U.S.)

MCANMicrobial Commercial Activity Notice (U.S.)

NDSL Non-Domestic Substances List (Canada)

NIOSH National Institute for Occupational Safety and Health (U.S.)

NOI Notice of Intent (NOI) (Canada)

NSN New Substances Notification (Canada)

NSNR New Substances Notification Regulations (Canada)

OSHA Occupational Safety and Health Administration (U.S.)

PCB Polychlorinated biphenyl(s)

PMN Premanufacture Notice (U.S.)

PNC Pre-Notice Consultation (Canada and U.S.)

RCC Regulatory Cooperation Council

SDS Safety Data Sheet

SNAc Significant New Activity (Canada)

SNAN Significant New Activity Notification (Canada)

SNUN Significant New Use Notice (U.S.)

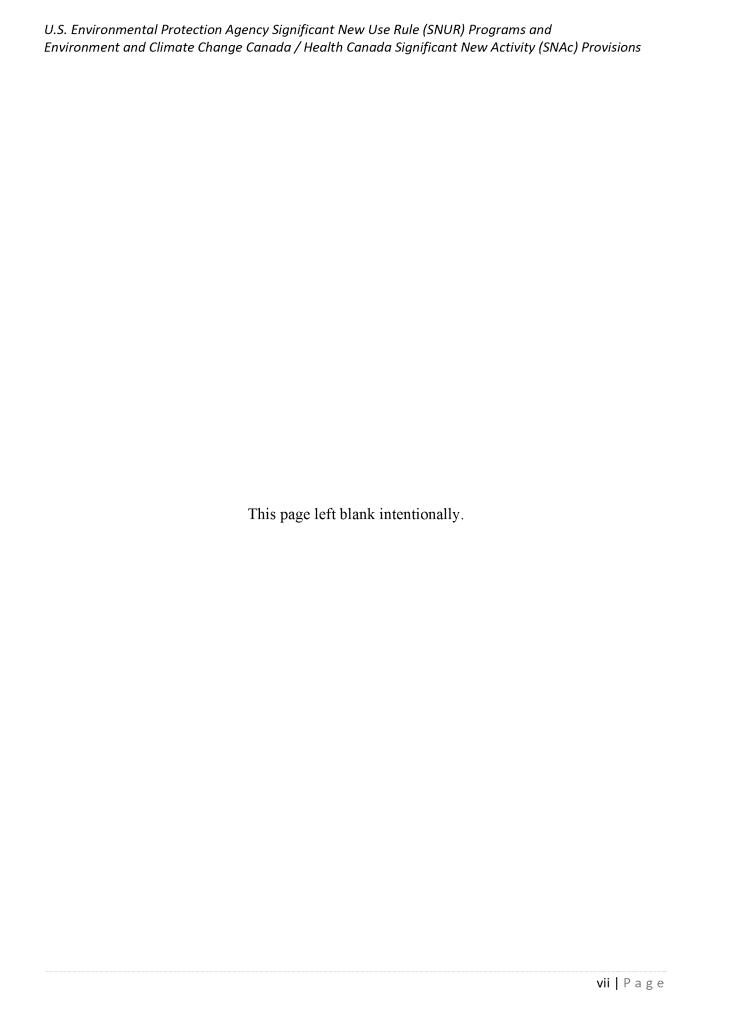
SNUR Significant New Use Rule (U.S.)

SRS Substance Registry Services (U.S.)

TERA TSCA Experimental Release Application (U.S.)

TSCA Toxic Substances Control Act (U.S.)

U.S. United States



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1. Introduction

1.1 Purpose

The purpose of this primer is to compile easy-to-use information for stakeholders potentially regulated under similar United States (U.S.) and Canadian requirements—Significant New Use Rules (SNURs) in the U.S. and Significant New Activity (SNAc) provisions in Canada. Information in this document will assist the regulated community in determining their compliance obligations, in engaging their supply chains in communication activities to facilitate compliance, and in sharing best practices for meeting SNUR and SNAc requirements.

1.2 Canada-United States Partnership and the Regulatory Cooperation Council (RCC) Process

Environment and Climate Change Canada (ECCC), Health Canada (HC), and the U.S. Environmental Protection Agency (EPA) collaborated in the implementation of a Regulatory Cooperation Council (RCC) Work Plan on Chemicals Management that focused on SNURs and SNAcs.¹

EPA and ECCC/HC held two roundtable meetings in September 2015, to convene stakeholders throughout the supply chain and facilitate discussions focused on the SNUR and SNAc programs. An overarching issue identified by the roundtable participants was the need for improved outreach and education, ranging from the basics of the



SNUR/SNAc programs to specific requirements for various stakeholders, especially for potentially less-informed stakeholder groups, such as foreign suppliers, and small, niche companies in the United States and in Canada. Educational materials are intended to ease compliance challenges of the various stakeholder groups. Key terms are defined in Section 4.

¹ https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/canada-united-states-regulatory-cooperation-council/workplan-stream-a-new-activity-provisions.html, accessed April 5, 2017.

U.S. Significant New Use Rules (SNURs): Existing and New Chemicals, under the Toxic Substances Control Act (TSCA)

2.1 Overview of SNURs

Section 5(a)(2) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors. These factors include:

- The projected volume of manufacturing (including import) and processing of a chemical substance;²
- The extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance;
- The extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance; and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.³

Under TSCA Section 5(a)(1), a person desiring to manufacture or process for commercial purposes the chemical substance or mixtures containing it for a significant new use identified in the SNUR must notify EPA at least 90 days prior to initiating manufacture or processing for the significant new use [see 40 CFR §721.5(a)(1)].

This notification initiates EPA's evaluation of the conditions of use, which means the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of, associated with the significant new use within the applicable review period. The person may not manufacture or process the chemical substance or mixture for the significant new use until EPA has conducted a review of the notice, made a determination on the notice under section 5(a)(3), and taken such actions as are required in association with that determination. SNURs can be promulgated for existing chemicals and new chemicals.

² Under TSCA Section 3, the definition of the term "manufacture" includes import into the customs territory of the United States. "Import" is included whenever "manufacture" is used in the context of TSCA in this document. ³ TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2).

⁴ https://www.epa.gov/tsca-inventory, accessed April 7, 2017.

⁵ https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-

2.2 "Existing" versus "New" ^{4,5}	

EPA classifies chemical substances as either "existing" or "new." "Existing" chemical substances are chemicals that were already in commerce when TSCA was enacted in 1976, and those that have undergone EPA review since then and have been added to the TSCA Chemical Substance Inventory. Any chemical substance that is not on the TSCA Inventory is classified as a new chemical. To determine if a substance is a new chemical, it is necessary to consult EPA's TSCA Inventory, which lists "existing" substances. EPA's Substance Registry Services can be used to determine if a chemical substance is listed on the public TSCA Inventory (see Section 2.10.1). The public version of the Inventory does not contain chemical identities that are claimed confidential. Someone with a valid commercial need for EPA to verify if a substance is on the Inventory can submit a Bona Fide Intent to Manufacture or Import Notice ("bona fide notice") to obtain a written determination from EPA. A chemical is considered new until it is reviewed under the TSCA New Chemicals Review program and is added to the Inventory.

The TSCA Inventory uses special flags to identify those substances on the Inventory that are the subject of an EPA rule or order promulgated under TSCA, as well as to indicate types of full or partial exemption from TSCA reporting requirements. The meanings of the flags are described on the EPA TSCA Inventory website.⁷

2.3 Substances Excluded from TSCA

Certain substances are generally excluded from TSCA, including: pesticides (when manufactured, processed, or distributed in commerce for use as such); foods, food additives, drugs, and cosmetics (when manufactured, processed, or distributed in commerce for use as such); tobacco and tobacco products; nuclear material; and munitions, provided that they do not also have uses subject to TSCA. For the most part, these substances are covered under other federal laws.

2.4 The Premanufacture Notice (PMN) Process

This discussion of the PMN process is relevant to SNURs, as prior to manufacture or processing of a new chemical, a notice must be filed with EPA under Section 5 of TSCA. A PMN must be submitted at least 90 days prior to initiating the activity. Significant New Use Notices (SNUNs)

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new, accessed September 1, 2016.

⁴ https://www.epa.gov/tsca-inventory, accessed April 7, 2017.

⁶ https://www.epa.gov/tsca-inventory/how-access-tsca-inventory, accessed September 1, 2016.

⁷ ibid.

submitted in response to a SNUR are handled the same way.

Further, there are similar TSCA section 5 notice requirements for the manufacture or processing of living microorganisms, which can also result in issuance of a SNUR. A Microbial Commercial Activity Notice (MCAN) is submitted for commercial "new" (intergeneric) microorganisms.^{8,9} Further information on MCANs and regulation of biotechnology under TSCA can be found in the EPA Fact Sheet, "Microbial Products of Biotechnology Summary of Regulations under the Toxic Substances Control Act."¹⁰

In general, TSCA Section 5 notices require that all reasonably ascertainable information on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure be included in the notice. In addition, EPA requires that the following information be submitted with the notice: any health and environmental information in the possession or control of the submitter, parent company or affiliates, and a description of any other applicable information known to or reasonably ascertainable by the submitter. See 40 CFR 720.45 and 40 CFR 720.50 for specific requirements. Electronic PMN software¹¹ allows manufacturers of TSCA chemical substances to use the Internet, through EPA's Central Data eXchange (CDX), to submit TSCA Section 5 notices to EPA.

2.5 New Chemical Determinations ¹²

Under TSCA,¹³ once EPA receives a PMN, MCAN, or significant new use notice (SNUN), the agency must make one or more of the following determinations:

• "Not likely to present an unreasonable risk" Determinations (See TSCA Section 5(a)(3)(C)) – In cases where EPA determines that a new chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use, EPA will notify the submitter of its decision under TSCA Section 5(a)(3)(C) and publish its findings in a statement in the Federal Register pursuant to TSCA Section 5(g). This includes cases for which EPA initially had concerns regarding the conditions of use of a PMN chemical substance but such concerns were subsequently adequately addressed through amendment of the PMN during the review period in

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⁸ Those who manufacture, process, and/or import microorganisms for research and development activities are required to submit a TSCA Experimental Release Application (TERA) in lieu of an MCAN.

⁹ Please see EPA's webpage for Filing a Biotechnology Submission under TSCA for further guidance: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/tsca-biotechnology-regulatory-and-policy-related, accessed November 4, 2016.

¹¹ https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn, accessed September 1, 2016.

¹² https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/regulatory-actions-under-tsca#5(f), accessed November 4, 2016.

¹³ https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act, accessed September 1, 2016.

- conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.
- "Insufficient Information" Determinations (See TSCA Section 5(a)(3)(B)(i)) In cases where EPA determines that the available information is insufficient to allow EPA to make a reasoned evaluation of the health and environmental effects of the new chemical substance or the significant new use, EPA will issue an order pending development of information under Section 5(e) of TSCA.
- "May present an unreasonable risk" Determinations (See TSCA Section 5(a)(3)(B)(ii)(I)) In cases where EPA determines that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the EPA Administrator under the conditions of use, EPA will issue an order pending development of information under Section 5(e) of TSCA. Most TSCA Section 5(e) Orders issued by EPA are Consent Orders that are negotiated with the submitter of the PMN, MCAN or SNUN.
- "Exposure-based" Determinations (See TSCA Section 5(a)(3)(B)(ii)(II)) In cases where EPA determines that the chemical substance is or will be produced in substantial quantities and either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, EPA will issue an order pending the development of information under section 5(e) of TSCA.
- "Presents an unreasonable risk" Determinations (See TSCA Section 5(a)(3)(A)) In cases where EPA determines that the chemical substance presents an unreasonable risk without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the EPA Administrator under the conditions of use, EPA will take the actions required under Section 5(f)the intended conditions of use, risks can be addressed through an amended PMN, EPA may issue a SNUR. Pursuant to Section 5(f), EPA may propose a rule under Section 6(a) or may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of the substance.

2.6 TSCA Section 5(e) and Section 5(f) Orders and SNURs

TSCA Section 5(e) and Section 5(f) Orders are typically Consent Orders negotiated with the submitter of the PMN. EPA makes the risk management decision and determines what restrictions are needed on the manufacture, processing, distribution in commerce, use, and disposal of the chemical. These restrictions, along with testing requirements to address the uncertainty, will be the basis of the Consent Order. Section 5(e) and 5(f) Orders are only binding on the PMN submitter for that chemical substance. The Consent Order typically contains some or all of the following requirements as conditions:

• Testing for toxicity or environmental fate once a certain production volume or time period is reached

- Use of worker personal protective equipment
- New Chemical Exposure Limits (NCELs) for worker protection
- Hazard communication language
- Distribution and use restrictions
- Restrictions on releases to water, air and/or land
- Recordkeeping.

After issuing a Section 5(e) or 5(f) Order, EPA generally promulgates a SNUR that requires notice to EPA by all other manufacturers and processors who wish to manufacture or process the chemical in a way other than described in the terms and conditions contained in the Order. The SNUR requires that manufacturers and processors of that chemical substance notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use." These new use designations are typically those activities limited or prohibited by the Section 5(e) or 5(f) Order. EPA will review the notice, make an appropriate determination on the notice, and taken such actions as are required in association with that determination.

SNURs not associated with Consent Orders. Promulgation of a significant new use rule (SNUR) can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns, as part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use. A SNUR requires that any manufacturer or processor – including the PMN submitter – who intends to undertake the activities subject to the SNUR must submit to EPA a significant new use notice. EPA must either conclude, following review of a significant new use notice (SNUN), that the activities are not likely to present an unreasonable risk under the conditions of use, or take appropriate action under section 5(e) or 5(f) to protect against any unreasonable risk. Because the review of the SNUN would be under the conditions of use, the review would factor in the conditions of use of the chemical specifically associated with the significant new use and, as appropriate, any other conditions of use relevant to the evaluation of significant new use under section 5(a)(3). A SNUR enables EPA to focus its technical analysis on the intended conditions of use of a chemical and defer further analysis of reasonably foreseen conditions of use until such time as the submitter (or any other entity) actually intends to undertake them. This is consistent with EPA's long-standing use of SNURs to defer detailed analysis of activities associated with chemicals until such time as someone indicates the intention to undertake the activities by submitting a SNUN.

2.7 Existing Chemicals	

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In addition to new chemicals, SNURs can also be promulgated for new uses of existing

chemicals. In these cases a SNUR would require notice to EPA, and that EPA conduct a review of the notice, make a determination on the notice and take such action as required in association with that determination before new uses could begin or resume. SNURs for existing chemicals typically occur in three circumstances: (1) the chemical has been phased out or taken off the market for certain uses or has not been manufactured for a certain use before, (2) the chemical is no longer being manufactured or processed for any use, or 3) there is a potential or likely use of a chemical that has not commenced. This second situation is often referred to as a "dead chemical SNUR." EPA can promulgate an existing chemical SNUR to ensure that no company will be able to manufacture or process the chemical for a specific use (circumstance 1) or for any

Example existing chemical SNUR: trichloroethylene (81 FR 20535)

EPA's June 2014 Work Plan Chemical Risk Assessment for TCE identified health risks associated with several trichloroethylene uses, including the arts and craft spray fixative use, aerosol and vapor degreasing, and as a spotting agent in dry cleaning facilities. In 2015, EPA worked with the only U.S. manufacturer of the trichloroethylene spray fixative product resulting in an agreement to stop production of the trichloroethylene-containing product and to reformulate the product with an alternate chemical. The trichloroethylene spray fixative product was being used by artists, picture framers, graphic designers, and printers to provide a water repellent and protective finish.

After the product was taken off the market, EPA then took action by issuing a SNUR to ensure that no other manufacturers enter the marketplace for TCE spray fixatives and other consumer uses unless EPA is notified of the significant new use, makes a determination and takes such actions as are required in association with the determination. The significant new use was determined to be the manufacture or processing for use in a consumer product, with an exception for ongoing use of trichloroethylene in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

Source: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/trichloroethylene-tce, accessed September 1, 2016.

use (circumstance 2) without prior notification to EPA, and EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination..¹⁴

2.8 Consumer Products and Articles addressed by SNURs

2.8.1 Consumer products

EPA defines consumer product at 40 CFR 721.3 as "a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation" and defines consumer as "a private individual who uses a chemical substance or any product containing the chemical

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¹⁴ https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/regulatory-actoins-under-tasca#SNUR, accessed September 1, 2016.

substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment." The key issue in this definition is that the chemical substance be sold or made available to the consumer for her or his own use; for example, the ink in a pen is made available for the consumer's use but the refrigerant that comes within the cooling system of a newly purchased car is not made available for the consumer's use.

2.8.2 Articles

Importers and processors of a chemical substance as part of an article are generally exempted from SNURs pursuant to 40 CFR 721.45(f), but the exemption can be made inapplicable in a particular SNUR if EPA makes an affirmative finding that there is reasonable potential for exposure to a chemical substance through an article or category of articles [see TSCA Section 5 (a)(5)].

For SNURs, the Agency relies on the following definition of article in 40 CFR 720.3(c): "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

2.8.3 Distinction between articles and consumer products

Articles can contain chemical substances that are considered consumer products. If an article makes available a chemical substance for consumer use, then it would be considered an article that contains a consumer product. An example would be an ink pen. The pen would be considered an article that contains ink that is made available to the consumer for her or his use.

An example of a difference between an article and a consumer product is automotive brake fluid. Brake fluid would be considered part of an article when already included within an automobile's brake lines, but the chemicals in the brake fluid would not be considered to be a consumer product because the automobile was not purchased for the brake fluid. When the brake fluid is purchased by a consumer at a car supply store to add to the automobile, that brake fluid would be considered a consumer product because it has been sold or made available to consumers for their use.

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2.9 SNUR Provisions

There are generally applicable SNUR provisions found in Subpart A of the Code of Federal Regulations (40 CFR part 721), which include requirements such as recordkeeping. In addition, the Subpart B provisions are citied for individual SNURs, some of which are described below.

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These include workplace protections, hazard communication programs, and restrictions on disposal and releases to water. As with all SNURs, they are applicable to manufacturers and processors. The corresponding Canadian topics and provisions are presented in Section 3.3 below.

2.9.1 Are there notification requirements for protection in the workplace and hazard communication?

New chemical SNURs often use standard language designating certain activities as significant new uses, set forth in Subpart B of part 721. The sections titled "Protection in the workplace" (40 CFR 721.63) and "Hazard communication program" (40 CFR 721.72) were modeled on Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) regulations. When subject to these requirements, a SNUN would be required before manufacture or processing associated with any use of the SNUR substance without establishing personal protective equipment or hazard communication programs described in those sections, including dermal protective equipment, respirators, a written hazard communication program, labeling, Safety Data Sheets (SDS), employee information and training, and certain precautionary statements. EPA has proposed in the *Federal Register* (see 81 FR 49598; July 28, 2016) changes to the TSCA SNUR regulations to align these regulations with revisions to the OSHA Hazard Communications Standard (HCS), which are proposed to be cross-referenced, and with changes to the OSHA Respiratory Protection Standard and the NIOSH respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals.

Section 5(f)(5) of TSCA addresses workplace exposure, instructing the EPA Administrator to consult with OSHA prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which EPA has made a determination under 5(a)(3)(A) or (B) to address workplace exposures.

2.9.2 Are there notification requirements for industrial, commercial, and consumer activities?

The section titled "Industrial, commercial, and consumer activities" can be found at 40 CFR 721.80. Using this provision, a SNUN would be required before manufacture or processing associated with a wide range of activities (25 are listed in the regulations), including use only in enclosed processes, a specific use, a specific production volume limit, a specific concentration limit, limits on the physical form in which a chemical may be used, use in a consumer product, and specific application method during use (e.g., aerosol). No further detail is provided in the regulations for the terms "industrial, commercial, and consumer activities," beyond the definitions provided generally in 40 CFR 721.3. EPA decided that in many instances it was more practical to simply identify the category of use that is of concern. Evaluation of a specific new use occurs at the time of SNUN submission.

2.9.3 Are there notification requirements for disposal?

The section titled "Disposal" can be found at 40 CFR 721.85. Using this provision, a SNUN

would be required before manufacture or processing associated with certain methods of disposal, such as incineration, landfill, or deep well injection.

2.9.4 Are there notification requirements for water releases?

The section titled "Release to water" can be found at <u>40 CFR 721.90</u>. Using this provision, a SNUN would be required before manufacture or processing associated with any predictable or purposeful release of a manufacture, processing, or use stream to surface waters associated with any use of the SNUR substance. This can be a requirement to notify if the Significant New Use (SNU) is any release, release without certain treatment methods, or release beyond a specified surface water concentration identified by EPA. <u>40 CFR 721.91</u> ("Computation of estimated surface water concentrations; instructions") provides guidance to the regulated community on how to compute estimated surface water concentrations from their facilities.

2.9.5 Are there recordkeeping requirements? 15

For each SNUR, EPA will specify appropriate recordkeeping requirements that correspond to the significant new use designations for the substance (e.g., recordkeeping requirements that relate to protection in the workplace, hazard communication, water release, etc.). Each manufacturer and processor of the substance shall maintain the records for 5 years from the date of their creation. Specific recordkeeping requirements are found in 40 CFR 721.125.

As explained in the July 27, 1989, rule pertaining to SNUR procedures, EPA sought to frame recordkeeping requirements in flexible, performance-oriented terms. Rather than specify the particular types of records that must be kept, the rule lists the general types of information required to document compliance with SNUR requirements. Thus, manufacturers and processors have discretion to determine which specific records must be retained. The records required to be maintained often will be normal business records, and EPA intends that normal business records will usually suffice. In a few cases, the generation of additional records will be required. It is the responsibility of the manufacturer or processor to assess the adequacy of existing records, add to them if necessary, and maintain them in a form accessible to EPA for the required length of time. EPA expects firms subject to SNUR requirements to exercise reasonable judgment in determining the steps necessary to document compliance with SNUR requirements. Records that are sufficient to document SNUR compliance in one case may not be sufficient in another. Table 1 in the 1989 preamble (see 54 FR 31303 and 31304) illustrates EPA's approach to recordkeeping by providing examples of the records that might document compliance with different SNUR requirements. These examples are intended merely to be illustrative. In many cases, the examples listed in that table would be sufficient to document SNUR compliance; in other cases, more or fewer records might be necessary.

The main purpose of the recordkeeping requirements is to know who is making the SNUR substance, how much are they making, and to whom they are distributing it. It is also important to have records that show compliance with any special provisions that a SNUR may have, such as any applicable water discharge limitations or workplace protective equipment. The figure on the following page describes the elements of a SNUR using siloxanes and silicones as an example.

¹⁵ 40 CFR 721.125, accessed September 1, 2016.

2.9.6 How are imports and exports affected?

As noted above, under TSCA Section 3, the definition of the term "manufacture" includes import into the customs territory of the United States. Imported chemicals may be in bulk or a part of a mixture or article, as TSCA Section 13 makes clear. Since imported chemicals are included in the definition of "manufacture," imported chemicals are generally subject to SNURs and other TSCA Section 5 reporting requirements, though there may be applicable regulatory exceptions. For example, someone is not subject to the notification requirements if the person imports or processes the substance as part of an article (unless otherwise specified in a specific SNUR) or manufactures or processes the chemical substance solely for export (see 40 CFR 721.45(f and 40 CFR 721.45(g)).

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¹⁶ 15 U.S.C. §2612 (2016), http://uscode.house.gov/view.xhtml?req=(title:15%20section:2612%20edition:prelim), accessed September 1, 2016.

¹⁷ EPA. (2016). "TSCA Requirements for Importing Chemicals." Retrieved from https://www.epa.gov/tsca-import-export-requirements, accessed July 27, 2016

Elements of a SNUR: Siloxanes and Silicones Example (§ 721.10888)

This SNUR is patterned after an accompanying TSCA section 5(e) consent order signed by EPA with the PMN submitter.

Section (a)(1) lists the substance to which the SNUR provisions apply. Substance(s) will generally be listed by

their PMN number and/or CAS number.

Section (a)(2) describes the significant new uses that apply to the listed substances. This means that any use other than those described in section (a)(2) requires notification and Agency review prior to being allowed to engage in that new use. In this particular example, that would include not using dermal protection in the workplace for persons reasonably likely to be exposed, use other than as a down converter for an optical filter, etc., or disposal other than by incineration in a permitted hazardous waste incinerator.

This SNUR is subject to the Protection in the workplace requirements with references to 40 CFR 721.63(a)(1),(a)(2)(i),(a)(3),(b), and (c). A general description of workplace and hazard communication requirements can be found in Section 2.9.1 of this primer.

This SNUR is subject to requirements for industrial, commercial, and consumer activities. The specific uses and processes are described here. More general information on requirements for industrial, commercial, and consumer activities can be found in Section 2.9.2 of this primer.

This SNUR is subject to disposal requirements. More general information on disposal requirements can be found in Section 2.9.3 of this primer.

Required recordkeeping requirements for all new chemical SNURs can be found in: 40 CFR 721.125(a), (b), and (c). Additional requirements in 721.125 correspond to the significant new use restrictions described above. Each manufacturer (including importer) and processor of the substance shall maintain the records for 5 years from the date of their creation. More general information on recordkeeping requirements can be found in Section 2.9.5 of this primer.

Source: 40 CFR 721.10888

§ 721.10888 Siloxanes and Silicones, 3-[(2-aminoethyl)amino)propyl Me, di-Me, reaction products with cadmium zinc selenide sulfide, lauric acid and oleylamine.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as siloxanes and silicones, 3-[(2-aminoethyl)amino)propyl Me, di-Me, reaction products with cadmium zinc selenide sulfide, lauric acid and oleylamine (PMN P-15-59; CAS No. 1623456-05-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) Protection in the workplace.
Requirements as specified in § 721.63 (a)(1),
(a)(2)(i), (a)(3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63 (a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(p)(three months and eighteen months). A significant new use of the substance is manufacture, process, or use the chemical substance other than as a down converter for an optical filter for light emitting diodes used in displays, or other than in a liquid formulation.

(iii) Disposal. Requirements as specified in § 721.85. It is a significant new use to dispose of the chemical substance other than by incineration in a permitted hazardous waste incinerator.

(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a), (b), (c), (d), (e), (i), and (j) are applicable to manufacturers and processors of this substance.

(2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

In order for a substance to enter the United States, importers must certify that their imported chemical substance either is subject to and complies with TSCA ("positive certification") or is not subject to TSCA ("negative certification"). ¹⁸ If a TSCA chemical substance is subject to a SNUR, the positive certification would include the fact that the imported substance is in compliance with the SNUR. Certain chemicals or chemicals that are a part of articles, are exempt from import certification (unless they are required by a specific rule under TSCA).

Under TSCA Section 12(b), any person who exports or intends to export from the United States a chemical substance or mixture subject to a SNUR must notify EPA of their intent to export, and EPA will share the information about the substance with the country of import.¹⁹ Certain chemicals, such as mercury, asbestos, hexavalent chromium, and polychlorinated biphenyls (PCBs), have specific export requirements or limitations.²⁰ Also see 40 CFR 761.97.

2.10 Resources to determine if a chemical substance is subject to a SNUR

EPA has multiple resources to determine whether or not a chemical substance is subject to a SNUR. These include Substance Registry Services (SRS) and ChemView.

2.10.1 EPA's Substance Registry Services (SRS)²¹

Substance Registry Services (<u>SRS</u>) is EPA's central system for information about substances that are tracked or regulated by EPA or other sources. It is a resource for basic information about chemicals, biological organisms, and other substances of interest to EPA and its state and tribal partners.

SRS makes it possible to identify which EPA data systems, environmental statutes, or other sources have information about a substance and which synonym is used by that system or statute. It becomes possible, therefore, to map substance data across EPA programs, regardless of a given naming convention.

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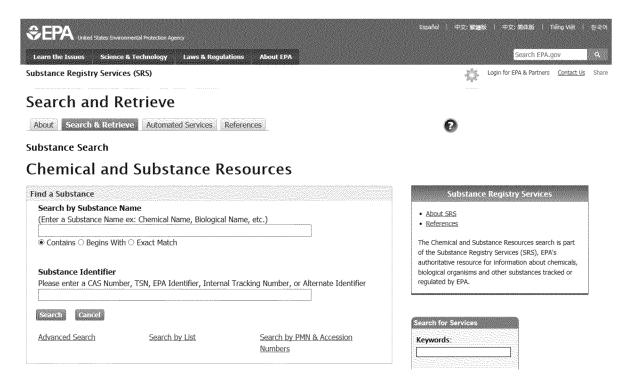
¹⁸ Customs and Border Protection's Import Regulations at 19 CFR 12.118 to 12.127, and 127.28.

¹⁹ EPA. (2016). "TSCA Section 6 Import/Export Requirements for Specific Chemicals." Retrieved from https://www.epa.gov/tsca-import-export-requirements/tsca-section-6-importexport-requirements-specific-chemicals, accessed July 27, 2016. See 40 CFR 707 subpart D for details.

²⁰ 15 U.S.C. §2611 (2016), http://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title15

section2611&num=0&saved=%7CKHRpdGxlOjE1IHNIY3Rpb246MjYwMSBlZGl0aW9uOnByZWxpbSk%3D%7C%7C%7C0%7Cfalse%7Cprelim, accessed September 1, 2016.

²¹ https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do, accessed September 1, 2016.



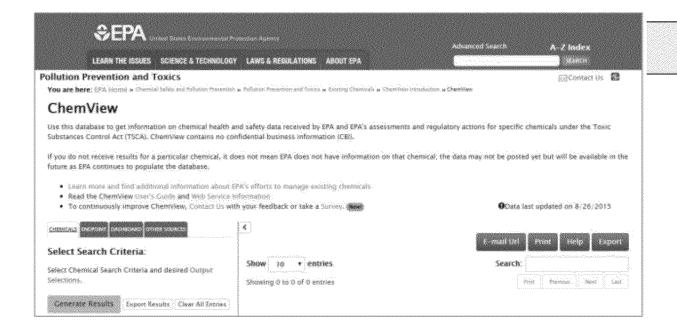
SRS can be accessed at the following link:

https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do

SRS can be searched for a specific chemical, with the results providing the type of regulation or other characteristic that affects the status of a chemical. If a chemical is associated with a SNUR, then the results will be presented as either "TSCA 5(a) Final SNUR" or "TSCA 5(a) Proposed SNUR." SRS users can also search for complete lists of the "TSCA 5(a) Final SNUR" chemicals and the "TSCA 5(a) Proposed SNUR" chemicals.

2.10.2 ChemView 22

EPA created <u>ChemView</u> to improve chemical safety and provide more streamlined access to information on chemicals. This database greatly improves access to health and safety data on chemicals regulated under TSCA. The database currently contains summary and in-depth information on more than 15,000 chemicals as well as proposed and final SNURs for over 2,800 chemicals. ChemView offers access to thousands of documents including data submitted to EPA, EPA assessments, and EPA actions such as test data, hazard characterizations, alternatives assessments, and TSCA regulatory actions. Users can search on a number of parameters, such as chemical identifier, endpoint, functional use, chemical category, and chemical group. For links to step-by-step instructions on how to use ChemView to determine if a chemical has a SNUR, please see Section 4.2.



²² <u>https://java.epa.gov/chemview</u>, accessed September 1, 2016.

ChemView can be accessed at the following link:

https://java.epa.gov/chemview

2.11 Significant New Use Notice (SNUN)²³

If EPA determines by rule that a use of a chemical substance is a significant new use, TSCA requires submission of a SNUN to EPA at least 90 days before a person manufactures or processes the chemical substance for that use.

If the manufacturer or processor intends to distribute the chemical in commerce for a significant new use, he or she must submit a SNUN, unless he or she notifies the recipient, in writing, that the substance has a SNUR, or the manufacturer knows that the recipient already knows this, or knows that it would be impossible for the recipient to undertake the new use.

While the manufacturer or processor is not legally obligated to enforce the recipient's actions, if at any time the manufacturer becomes aware of the fact that the recipient is engaging in the new use without submitting a SNUN, then the manufacturer needs to stop supplying the SNUR substance to that recipient and the manufacturer may also need to submit a SNUN (exact requirements are detailed at 40 CFR 721.5). An example of this would be a SNUR that does not allow for the spray application of the chemical and the recipient of the chemical undertakes spray application without submitting a SNUN.

The SNUN uses the same form and electronic submission method as the PMN, and initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal, as required by the PMN process (see section 2.4). EPA encourages persons to consult with EPA before submitting a SNUN. As part of this optional Pre-Notice Consultation (PNC), EPA would discuss specific data that it believes may be useful in evaluating a significant new use.

2.11.1 Who is exempted from submitting a SNUN?

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²³ https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-usenotice, accessed September 1, 2016.

Industrial and commercial users are not subject to SNURs if they are neither manufacturing nor processing the chemical substance for which a SNUR exists. They are not required to submit SNUNs or keep records.

Further exemptions for research and development, impurities, byproducts, and articles can be found at 40 CFR 721.45.

<u>2.11.2 Who is exempted from submitting a SNUN when distributing a chemical substance with a SNUR in commerce?</u>

A person who intends to manufacture or process for commercial purposes a chemical substance identified within 40 CFR part 721, subpart E, and intends to distribute the substance in commerce is nonetheless **not required** to submit a SNUN if that person can document one or more of the following as to each recipient of the substance from that person:

- 1. The person has notified the recipient, in writing, of the specific section in subpart E of Part 721 that identifies the substance and its designated significant new uses.
- 2. The recipient has knowledge of the specific section in subpart E of Part 721 that identifies the substance and its designated significant new uses.
- 3. The recipient cannot undertake any significant new use described in the specific section in subpart E of Part 721.²⁴

Even if a person is not required to submit a SNUN under the circumstances above, that person would have to submit a SNUN if that person:

- 1. Knows at the time of commercial distribution that a recipient intends to engage in a significant new use without submitting a SNUN (40 CFR 721.5(b)); or
- 2. At any time thereafter, has knowledge that a recipient is engaging in a significant new use without submitting a SNUN, subject to limited exception (40 CFR 721.5(d)(1)).

Additionally, a person who processes a chemical substance identified within 40 CFR Part 721, Subpart E for a significant new use of that substance is **not required** to submit a SNUN if that person can document each of the following:

- 3. The person does not know the specific chemical identity of the chemical substance being processed, and
- 4. The person is processing the chemical substance without knowledge that the substance is identified in 40 CFR Part 721, Subpart E.

24	40 CFR	721.5,	accessed	September	1, 2016.

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2. Canada's Significant New Activity (SNAc) Provisions²⁵

3.1 Canadian Authority for SNAcs

The Significant New Activity (SNAc) provisions of the <u>Canadian Environmental Protection Act</u>, 1999 (CEPA) trigger an obligation for a person to provide the Government of Canada with information about a substance when proposing to use, import, or manufacture the substance for a significant new activity. The government then assesses the substance for potential risks to human health and/or the environment. The decision to apply the SNAc provisions for a specific activity in relation to a substance is based on risk. Where potential changes in exposure to a substance could occur due to the "significant new activity," SNAc provisions allow for an assessment to take place prior to the commencement of these activities. If risks are identified during the assessment, the government could impose management measures. For further details, sections 80-89 in Part 5 of CEPA²⁷ list requirements related to Substances and Activities New to Canada and sections 104 to 115 in Part 6 of CEPA²⁸ list requirements related to Animate Products of Biotechnology.

Current information on SNAc provisions can be accessed on the ECCC webpage on "The Significant New Activity Provisions under CEPA."²⁹

3.1.1 What are "significant new activities"?

A "significant new activity" is any activity that results or may result in a higher quantity or concentration of a substance into the environment or in exposing the environment in a different manner or circumstance, which could affect environmental or human exposure to the substance. What constitutes a significant new activity is specific to each substance and is described in the relevant SNAc publication in the *Canada Gazette*. It is important to note that the definition of a "significant new activity" in a SNAc publication for a given substance could include more than one activity.

3.1.2 What substances are subject to SNAcs?

SNAc provisions can be applied to the full suite of substances regulated under CEPA, and defined in Section 3 of the Act. This includes: chemicals, polymers, biopolymers, biochemicals, nanotechnology and animate objects of biotechnology (living organisms). Section 3 of CEPA

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²⁵ https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9EFCCB36-1, accessed August 1, 2016.

²⁶ http://laws-lois.justice.gc.ca/eng/acts/c-15.31/, accessed April 7, 2017.

²⁷ https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-1&offset=5&toc=hide%20-%20t5, accessed April 7, 2017.

²⁸ https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-

<u>1&offset=6&toc=hidehttps://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-1&offset=6&toc=hide, accessed April 7, 2017.</u>

²⁹ http://www.ec.gc.ca/lcpe-cepa/default.asp?Lang=En&n=9EFCCB36-1%20-%20q3, accessed April 7, 2017.

also indicates that mixtures: manufactured items; and animate matter/mixtures contained in effluents, emissions or wastes are not considered "substances" for the purpose of notification requirements under SNAc provisions. However, it should be noted that individual components of a mixture could be notifiable under the SNAc provisions. For further clarification regarding substances, manufactured items and consumer products, please refer to the box at right.

Subsections 81(6) and 106(6) of CEPA^{30,31} exempt certain uses of substances from notification under the SNAc provisions including: using a substance to manufacture or importing a substance for use in pesticides, fertilizers, and feeds since notification of these uses is required under other

SNAcs and Consumer Products/Manufactured Items

Consumer products and manufactured items are treated differently by SNAcs. The following explains how they are different.

In Canada, where the term "consumer product" is used in a SNAc Notice or Order, the term normally references the *Canada Consumer Product Safety Act* (CCPSA). Section 2 of the Act defines a consumer product as "a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging." This definition includes products used/provided in commercial settings (e.g., daycare facilities, hotels, etc.) as well as non-exempt commercial products that may be purchased by a consumer. The term "consumer product" includes only those products to which the CCPSA applies (Section 4 and Schedule 1 of the CCPSA list products which are excluded from the definition). If products to which the CCPSA does not apply are of potential concern, they will be specifically described in the SNAc definition.

A manufactured item is defined under section 3 of CEPA as "...formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape of design." Where the substance is in a manufactured item, it is generally excluded from notification under SNAc provisions. However, substances in fluids and particles contained within a manufactured item may be notifiable if they are released during normal use in an uncontrolled or dispersive manner.

Source: Canadian Environmental Protection Act (1999); Guidelines for the Notification and Testing of New Substances, Chemicals and Polymers (2005) and; Canada Consumer Product Safety Act

Acts of Parliament. Additional exclusions are listed in these subsections and include: transient reaction intermediates that are not isolated; impurities, contaminants and partially unreacted materials; and incidental reaction products.

For notification and assessment purposes, CEPA distinguishes between "new" substances and "existing" substances. The Domestic Substances List (DSL) is a compilation of all known

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³⁰ <u>https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-1&offset=5&toc=hide,</u> accessed April 7, 2017.

³¹ https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-1, CC0DE5E2-1&offset=6&toc=show, accessed April 7, 2017.

substances that were in Canadian commerce between 1984 and 1986 or that have been added to the DSL in accordance with CEPA. The DSL is the sole basis for determining whether a substance is new for the purposes of the Act and the Regulations and is amended regularly. A substance not listed on the DSL is considered to be a new substance in Canada. Any person who intends to import or manufacture a new substance in Canada is required to notify under the *New Substances Notification Regulations* (Chemicals and Polymers) [NSNR (Chemicals and Polymers)] and the *New Substances Notification Regulations* (Organisms) [NSNR (Organisms)]. Following the assessment under these regulations of a new substances, the SNAc provisions can be applied. For information on the notification of new substances, refer to ECCC's *Evaluating New Substances* webpage.³²

Substances listed on the DSL are considered to be existing substances in Canada. Under the Chemicals Management Plan,³³ prioritized existing substances have been subject to risk assessment and, where warranted following a risk assessment conclusion, subject to SNAc provisions.

The Non-Domestic Substances List (NDSL) is an inventory of substances that are not on the DSL, but are accepted as being in use internationally. The NDSL is based on the USEPA's TSCA Chemical Substance Inventory. Substances that are not on the DSL, but are listed on the NDSL, are subject to the NSNR (Chemicals and Polymers) and NSNR (Organisms). However, they are subject to fewer information requirements.

3.1.3 When are SNAc provisions put in place? 34

The decision to use the SNAc provisions is risk-based. The SNAc provisions are considered for use once a new or an existing substance has been reviewed in accordance with CEPA, and the assessment conclusion finds a reasonable suspicion that new activities with a substance may result in new or increased risks to the environment and/or human health. That suspicion could be based on a number of factors including the specific properties of the substance, the function of the substance, or the presence of the substance in markets in other jurisdictions.

SNAc provisions could also be applied to an existing substance if it is no longer in Canadian commerce or the substance has very limited, well managed uses. In this case, SNAc provisions would be applied to monitor any potential future new activities with the substance prior to the start of these activities to assess the risks they pose.

For further details about when SNAc provisions are applied, refer to the *Policy on the Use of Significant New Activity Provisions of the Canadian Environmental Protection Act, 1999.*³⁵

3.1.4 How are SNAcs published?

All SNAc notices and orders are published in the Canada Gazette, the official newspaper of the

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³² http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?.asp?lang=En&n=AB189605-1, accessed June 11, 2017

http://www.chemicalsubstanceschimiques.gc.ca/index-eng.php, accessed April 5, 2017.

http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5CA18D66-1, accessed November 17, 2016.

³⁵ https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5CA18D66-1

Canadian Government. There are different procedures and policies in place for publishing SNAc requirements related to new and existing substances.

The following graphic provides an example of a SNAc publication and identifies the information contained in each section.

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Elements of a SNAc Publication: Quinoline Example (SOR/2015-73)

SNAcs may be published in either the Canada Gazette Part I 2015-04-22 Canada Gazette Part II, Vol. 149, No. 8 Gaz(Notices - for SNAcs on substances not on the DSL; Notices of Intent - for SNAcs on substances on the DSL) or Canada Gazette, Part II (Orders - for SNAcs on DSL substances). In 2. Part 2 of the List is amended by adding the following in all cases, information related to the substance identity, numerical order: definition of significant new activities, and data requirements for SNANs is in the same format. Column 1 Column 1 is where the substances are listed to which the Significant new activity for which substance is subject to SNAc provisions apply. Substances will be listed by their CAS Substance subsection 81(3) of the Act RN and are followed by a flag: the "S" flag indicates a new 91-22-5 8' Any activity involving, in any one calendar year, more than 100 kg of the substance quinoline in its isolated form, namely, substance newly added to the DSL for which there are existing SNAc provisions in force; or the "S prime" (S') flag quinoline that is extracted from naturally occurring sources or that indicates that the substance was already listed on the DSL is manufactured. and SNAc provisions have been applied to that existing For each proposed significant new activity, the following: substance. information must be provided to the Minister at least 180 days before the day on which the quantity of the substance exceeds In the example here, the (S') flag is indicated, specifying that 100 kg in any one calendar year: this is an existing substance for which SNAc provisions are in (a) a description of the proposed significant new activity in relation to the substance; (b) the anticipated annual quantity of the substance to be used; Item 1 under Column 2 is where the definition of what (c) if known, the three sites in Canada where the greatest quantity constitutes a "new activity" is described in the SNAc Notice of the substance is anticipated to be used or processed and the or Order. It is important to review this section to see if a estimated quantity by site; person's intended use of the substance is included in this (d) the information specified in items 3 to 7 of Schedule 4 to the New Substances Notification Regulations (Chemicals and Polymers); In this example, the significant new activity is defined as (e) the information specified in paragraphs 2(d) to (f) and $\delta(a)$ to "any activity involving more than 100 kg of the substance in (g) of Schedule 5 to those Regulations; its isolated form...extracted from naturally occurring sources (f) the information specified in paragraph 11(b) of Schedule 6 to or that is manufactured." those Regulations: (g) the products and, if known, end-use products that are Item 2 under Column 2 is where the submission anticipated to contain the substance, the intended use of those products and the function of the substance in those products; requirements are listed for each new use under the SNAc provisions. This initial section indicates when the (h) a summary of all other information or test data in respect of information must be submitted to the Minister. In this the substance that are in the possession of the person proposing the significant new activity, or to which they have access, and particular case the requirement is "...180 days before the day on which quantity exceeds 100 kg in any one calendar that are relevant to identifying hazards of the substance to the environment and human health and the degree of environmental and public exposure to the substance; Sub-items under Item 2, here listed as (a) through (k), (i) the identification of every government department or agency, either outside or within Canada, to which the person proposing indicate the information that must be provided to the Minister within the timeframes specified in Item 2. the significant new activity has provided information regarding Information requirements listed are often made with the substance and, if known, the department or agency's file number and, if any, the outcome of the assessment by the department or agency and the risk management actions in relation to the substance imposed by the department or agency; reference to Schedules under the New Substances Notification Regulations (NSNR), which have a similar process and information submission requirements. The (j) the name, civic and postal addresses, telephone number and, regulations and associated schedules can be found by if any, the fax number and email address of the person proposing searching the Canada Gazette. the significant new activity and, if any, the person authorized to act on their behalf; and Item 3 under Column 2 identifies the length of time (k) a certification stating that the information is accurate required by the Government to review and assess the and complete, dated and signed by the person proposing the significant new activity, if they are resident in Canada or, if not, information provided. The assessment period can range from 90 to 180 days. In this particular case, the assessment by the person authorized to act on their behalf period is 180 days after the day on which the information is 3. The above information will be assessed within 180 days after received for that particular submission. the day on which it is received by the Minister.

Source: Canada Gazette (2015) Part II: Vol.149, No.8, Page 2, SOR/2015-73

SNAc notices for new substances are published in the *Canada Gazette*, Part 1 (Notices and Proposed Regulations) within 90 days after the expiry of the assessment period of the related new substance notification. Once published, the SNAc notice normally comes into force immediately. There is no formal comment period prior to or after the publication of the SNAc notice. A notifier can submit, at any time, information that could have a bearing on the notice. ECCC and HC will review this information and take appropriate action, if required.

SNAc notices for existing substances are published in the *Canada Gazette*, in two parts. First in Part I, a Notice of Intent (NOI), which is considered a draft SNAc Order, is published for a 60-day comment period. This is an opportunity for stakeholders to provide comments to inform the Canadian Government of any information relating to the existing substance and its current use. Following the consultation period, the SNAc is finalized and a final Order applying the SNAc provisions to the substance is published in *Canada Gazette*, Part II (Official Regulations). Generally the SNAc Order is in force the day it is published, but occasionally entry into force can be delayed.

3.1.5 Available resources to determine if SNAc provisions have been applied to a substance

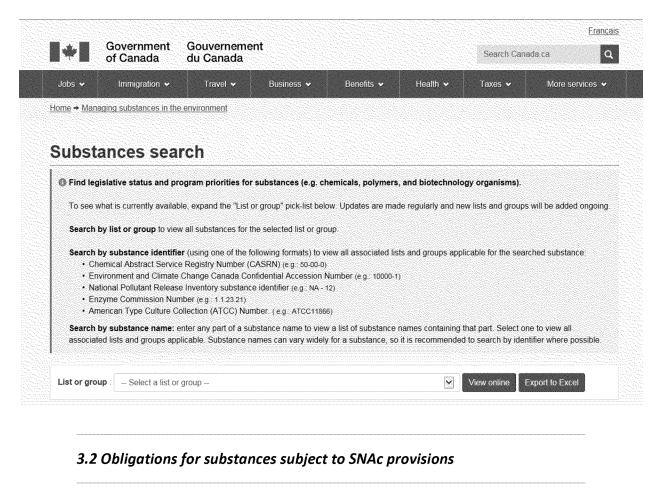
The <u>Substances search</u> tool (see example graphic below) can be used to identify substances on the DSL, substances on the NDSL, as well as substances subject to the SNAc provisions.³⁶ Substances listed on the DSL that are subject to SNAc provisions will be identified using either "S" or "S"" (S prime) flags. The image below is a screen shot from the Substances search tool on the Government of Canada website. Users can search for substances using a specific list or group (DSL, NSNR, SNAc), a substance identifier (CASRN), or a substance name.

The <u>Comprehensive List of Substances that are Subject to the Significant New Activity Provisions</u> also provides a list of substances subject to the SNAc provisions and links to SNAc publications in the *Canada Gazette*.³⁷ See Section 4 *Resources and Other Supporting Materials* for a list of webbased resources.

Substances listed on the confidential portion of the DSL are published with confidential accession numbers. SNAc notices published for such substances, as well as those published for substances not on the DSL where the substance identity is confidential, are referenced by their confidential accession numbers. Anyone who intends to engage in a significant new activity for a substance that they believe to have been published with a confidential accession number may seek confirmation from the Substances Management Information Line (see Section 4, *Resources and Other Supporting Materials*, for contact information).

³⁶ http://pollution-waste.canada.ca/substances-search, accessed June 14, 2017.

³⁷ http://ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=0F76206A-1, accessed April 7, 2017.



3.2.1 Are there SNAc obligations to notify recipients?

Sections 86 and 111 of CEPA outline the requirement for mandatory recipient notification for certain substances subject to SNAc provisions. Under these sections, when transferring possession of a substance that is not listed on the DSL and that is subject to SNAc provisions (including if the substance is in a mixture), all recipients must be notified of the obligation to comply with SNAc provisions. This notification enables recipients to determine their own compliance obligations with respect to the SNAc.

For substances on the DSL subject to a SNAc, it is recommended that this notification also be carried out to allow recipients to be in a position to determine their own SNAc compliance obligations. Additionally, notifying recipients ensures open communication within the supply chain, allowing recipients to inform suppliers/distributors about the SNAc and their use of the substance.

3.2.2 What are Significant New Activity Notifications (SNANs)?

A Significant New Activity Notification (SNAN) is the information submitted to the government in compliance with a SNAc Notice or Order. The SNAN must contain all of the information prescribed in the published Notice or Order. SNANs must be submitted to the Minister of the

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Environment, through Program Development and Engagement Division at ECCC.³⁸

Who needs to submit a SNAN?

If a person's proposed activities with a substance are captured by the definition of a SNAc Notice or Order, and are not subject to any exemptions (see Section 3.1.2), that person is required to submit a SNAN to the government for assessment prior to the commencement of these activities. The foremost source of information to determine if a SNAc applies is the SNAc Notice or Order. Specific timeframes for submission of a SNAN are listed in the specific SNAc publication.

For substances not on the DSL and subject to SNAc provisions, those persons who intend to use the substance should review the description of the significant new activity in the SNAc publication to determine whether their proposed activities meet the definition of a significant new activity. Otherwise, substances not listed on the DSL do have separate notification requirements under the NSNR (Chemicals and Polymers) or the NSNR (Organisms) before they are imported or manufactured.

For substances on the DSL and subject to SNAc provisions, manufacturers, importers, and users of substances who are planning an activity in relation to a substance must determine whether a SNAN notification is required for their planned activity. Anyone with any questions regarding whether or not a SNAc applies to their activities are encouraged to contact the Substances Management Information Line (see Section 4, *Resources and Other Supporting Materials*).

A company can submit a SNAN on behalf of its customers (known as an "umbrella SNAN"). For example, in cases where a person receives possession and control of a substance from another person, the recipient may not be required to submit a SNAN under certain conditions if the activities were covered by the original SNAN submitted by the supplier. The Substances Management Advisory Note, Clarification in relation to the submission of Significant New Activity Notifications in application of the Canadian Environmental Protection Act, 1999, provides more detail on this subject.³⁹

What is required in a SNAN?

The information required to complete a SNAN is unique to each substance and is described within the *Canada Gazette* publication that applies the SNAc provisions to the substance. Many of the information requirements of SNAcs reference the standard schedules of the <u>NSNR</u> (Chemicals and Polymers) and the <u>NSNR</u> (Organisms).

Additional guidance on preparing a SNAN can be found in the <u>Guidelines for the Notification</u> and <u>Testing of New Substances (Chemicals and Polymers)</u> and the <u>Guidelines for the</u>

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³⁸ http://www.ec.gc.ca/lcpe-cepa/default.asp?Lang=En&n=9EFCCB36-1%20-%20ci%20-%20ci, accessed April 7, 2017.

³⁹ http://ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=CC526AE6-1, accessed April 7, 2017.

⁴⁰ http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/index.html, accessed April 7, 2017.

⁴¹ http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-248/index.html, accessed April 7, 2017.

Notification and Testing of New Substances (Organisms). 42,43

Although a specific reporting form is not available for submitting a SNAN, nor is it required, sections of the New Substances Notification (NSN) Reporting Form may be used as appropriate.⁴⁴

A Pre-Notification Consultation (PNC) is available for notifiers who wish to consult with the program during the planning or preparation of their SNAN to discuss any questions or concerns about the prescribed information and test plans. To request a PNC or receive more information, contact the <u>Substances Management Information Line.</u>⁴⁵

What is a SNAN Assessment?

Once a SNAN is submitted to the government, the Minister of Environment and the Minister of Health assess the information provided, as well as other available information, to determine whether the substance could pose a risk to the environment and/or human health, and whether further risk management measures are required.

Prescribed periods for SNAN assessments are indicated in a SNAc publication. The assessment period for SNANs can vary, but typically for a new substance SNAN it is 90 days,⁴⁶ while the assessment period for organism SNANs is 120 days.⁴⁷ The time required to complete an assessment could vary depending on a number of factors, including the information provided in the SNAN and the complexity of the substance and/or activities being assessed. The Ministers do have the power to extend the assessment period for a SNAN as identified in Section 83(4) and Section 108(4) of CEPA,⁴⁸ to a maximum of the same number of days specified in the original assessment period identified in the SNAc Notice or Order. The new activity cannot be undertaken until the assessment period of the SNAN has expired.

What is the outcome of a SNAN?

The outcome of the SNAN assessment determines if the substance could be toxic or not under Section 64 of CEPA, 49 and also informs decisions made concerning risk management measures for the substance and/or activity if required. There are generally two potential outcomes for a SNAN: toxic or not toxic.

If the assessment concludes a substance could be toxic, risk management measures would be imposed on the substance or activity to address the new or increased risk to the environment and/or human health. For new substances this could include conditions or prohibitions under

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⁴² http://publications.gc.ca/site/eng/280464/publication.html, accessed April 7, 2017.

http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=22FC25C8-1%20-%20a12, accessed April 7, 2017.

⁴⁴ http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=50E76A87-1, accessed April 7, 2017.

⁴⁵ http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9EFCCB36-1%20-%20ci, accessed April 7, 2017.

⁴⁶ http://laws-lois.justice.gc.ca/PDF/C-15.31.pdf, accessed April 7, 2017.

⁴⁷ http://laws-lois.justice.gc.ca/PDF/C-15.31.pdf, accessed April 7, 2017.

⁴⁸ http://laws-lois.justice.gc.ca/PDF/C-15.31.pdf, accessed April 7, 2017.

⁴⁹ https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=CC0DE5E2-1&offset=5&toc=hide, accessed April 7, 2017.

Section 84 of CEPA. For existing substances, a range of tools could be implemented, including: voluntary agreements, addition to the list of toxic substances of CEPA (Schedule 1), regulations, guidelines, codes of practice, and pollution prevention plans. The SNAcs may also be amended to exclude those specific activities because they are being risk managed by alternate means, and to avoid duplicative notification.

When the assessment concludes a substance is not likely to be toxic following a SNAN assessment, the SNAc would be amended to exclude those activities that are not of concern and for which notification is no longer required, or the SNAc could possibly be rescinded, to allow companies to undertake those activities freely.

3.3 Additional SNAc Information

This section describes comparable requirements and other information for SNAcs, similar to those described for US SNURs in Section 2.9.

3.3.1 Are there requirements for protection in the workplace and hazard communication?

Health Canada contributes to occupational health and safety (OHS) issues by administering the Workplace Hazardous Materials Information System in partnership with the federal, provincial and territorial (FPT) OHS regulatory agencies. Labor legislation falls under the jurisdiction of Canada's FPT OHS agencies. Consequently, SNAcs do not have requirements for protection in the workplace and hazard communication.

3.3.2 Are there requirements for industrial, commercial, and consumer activities?

The CEPA and the CCPSA do not set out regulations regarding new activities related to specific industrial, commercial, and consumer significant new activities as is done under TSCA for new uses. These types of activities can be described in a SNAc in three basic ways: (1) broadly applicable, (2) broadly applicable with exclusions, and (3) targeted. The table below presents an example of each type. A SNAc definition could be broad and define a significant new activity as any activity with the substance above a specific threshold. Similarly, a specific activity regarding the use of a substance in a consumer product could be targeted. It depends on the substance and for which activities the Canadian government is trying to obtain information for evaluation. It is incumbent on companies who may be impacted to review the SNAc publication carefully to determine if their activity could be included in the definition of significant new activities.

3.3.3 Are there disposal requirements?

There are usually no specific requirements for disposal in SNAc publications. Also, as outlined in Section 3.1.2, Section 3 of CEPA lists mixtures as part of effluents, emissions or wastes as not considered substances for the purposes of notification requirements under SNAc provisions. However, individual components of mixtures could be notifiable in a SNAc under the definition of the significant new activity.

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3.3.4 Are there release-to-water requirements?

Release-to-water requirements are not typically managed by SNAc provisions as they are with SNURs. There are other regulatory risk management tools that the Canadian government uses that have similar release-to-water requirements (e.g., Ministerial Conditions). Moreover, there are other federal and provincial laws, such as the Fisheries Act, which could apply to these releases. Persons engaged in activities which include releases to water should follow the requirements that apply in the jurisdiction where their activities take place.

3.3.5 Are there recordkeeping requirements?

Typically, there are no general record-keeping requirements for SNAcs, unless explicitly stated in the SNAc publication.

Examples of Different Types of S	Significant New Activity Definitions Published in SNAcs	
Broadly Applicable (any use, manufacture or import above a threshold)	Order 2013-87-03-01 (CAS 116-66-5): "Any activity involving, in any one calendar year, more than 100 kg of the substance 1H-indene, 2,3-dihydro-1, 1,3,3,5-pentamethyl-4,6-dinitro"	
	Canada Gazette, Part II: Vol.147, No.14, Page 1904	
Broadly Applicable, with exclusions (any use, manufacture or import activity above a threshold other than x, y, z)	Order 2013-87-11-01 (CAS 88-72-2): "Any activity involving, in any one calendar year, a total of more than 100 kg of the substance Benzene, 1-methyl-2-nitro-, other than an activity involving its use in the manufacture of explosives." Canada Gazette, Part II: Vol.148, No.2, Page 183	
Targeted (specific activity with threshold)	• SNAc Notice No. 18020:a significant new activity is the use of the substance in a quantity greater than 100 kg per calendar year in any cosmetic or drug as defined in section 2 of the Food and Drugs Act, or in any natural health product as defined in subsection 1(1) of the Natural Health Products Regulations.	
	Canada Gazette, Part I: Vol.149, No.23, Page 1096	

4.0 Resources and Other Supporting Materials

EPA Resources		
EPA website	https://www.epa.gov/	
EPA's ChemView	https://www.epa.gov/assessing-and-managing- chemicals-under-tsca/introduction-chemview	
EPA's Substance Registry Services (SRS)	https://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do	
SNUNs are reported using the standard e-PMN form and are subject to a 90-day review process similar to that for a PMN. Access to the e-PMN form	https://www.epa.gov/reviewing-new-chemicals- under-toxic-substances-control-act-tsca/how- submit-e-pmn	

ECCC/HC I	Resources
SNAc Webpage	https://www.ec.gc.ca/lcpe- cepa/default.asp?lang=En&n=9EFCCB36-1#q9
Comprehensive Listing of Substances that are Subject to Significant New Activity Provisions	http://ec.gc.ca/subsnouvelles- newsubs/default.asp?lang=En&n=0F76206A-1
Substances Search Tool (chemicals, polymers and organisms)*	http://pollution-waste.canada.ca/substances- search/Substance?Error=1&Id=1257085-86- 1&ExactMatch=False
Canada Gazette general website – where SNAc Orders and Notices are published	http://www.gazette.gc.ca
Government of Canada RCC webpage	http://www.chemicalsubstanceschimiques.gc.ca/plan/council-conseil-cooperation/index-eng.php
HC general website	http://www.hc-sc.gc.ca
ECCC general website	https://www.ec.gc.ca
Substances Management Information Line	Toll-free in Canada: 1-800-567-1999 Outside Canada: 1-819-938-3232 Fax: 1-819-938-5212 Email: ECCC.substances.ECCC@canada.ca

^{*} The Substances search tool is a searchable database of substances previously published in the *Canada Gazette* (e.g., substances on the DSL, NDSL, and new and existing substances subject to the SNAc provisions). *Canada Gazette* publications are the official source for SNAc publications.

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U.S. Environmental Protection Agency Significant New Use Rule (SNUR) Programs and
Environment and Climate Change Canada / Health Canada Significant New Activity (SNAc) Provisions

4.1 Explanation of Key Terms		

Canada Notice of Intent (NOI) – An NOI to amend the DSL is published in the *Canada Gazette*, Part I (CG I), followed by a public comment period, and publication of an Order amending the DSL in the *Canada Gazette*, Part II (CG II). The SNAc provisions apply as soon as the Order is registered (i.e., in force) unless the Order indicates otherwise.

Canada Significant New Activity (SNAc) – An activity conducted with a substance in a different quantity, concentration, or in different circumstances that could affect the environment or human exposure. What constitutes a significant new activity (or activities) is specific to each substance and is found in the relevant SNAc publication in the *Canada Gazette*.

Canada Significant New Activity Notification (SNAN) – If a person's proposed activities with a substance are captured by the definition of a significant new activity, that person is required to submit a SNAN to the government for assessment within the specified regulatory time period prior to the new activity being undertaken.

Canadian Environmental Protection Act, 1999 (CEPA) – An Act respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development.

- **U.S. Premanufacture Notice (PMN)** Anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose is required by TSCA to provide EPA with notice before initiating the activity. A PMN must be submitted at least 90 days prior to the manufacture of the new chemical or significant new use. An online version of the PMN form is available on EPA's website in an electronic (e-PMN) format.
- U.S. Significant New Use Notice (SNUN) A manufacturer (including importer) or processor intending to engage in a designated significant new use must submit a SNUN to EPA at least 90 days before manufacturing or processing the chemical for the significant new use. This notification initiates EPA's evaluation of the chemical within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.
- **U.S. Significant New Use Rule (SNUR)** –EPA issues regulations designating significant new uses of a chemical so that Agency review occurs before chemical substances are used in new ways that might create environmental and human health concerns. Once EPA designates a significant new use for a chemical, manufacturers and processors of that chemical who wish to initiate that use must submit a SNUN before manufacturing or processing the chemical for the significant new use.
- **U.S. Toxic Substances Control Act (TSCA)** Provides EPA with authority to establish reporting, recordkeeping, testing requirements, and restrictions relating to chemical substances or

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mixtures. TSCA addresses the production, importation, use, and disposal of specific chemicals.

Importer (TSCA) – Any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the U.S. Importer includes the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his/her behalf.

Manufacturer (TSCA) – A person who imports, produces, or manufactures a chemical substance.

Processor (TSCA) – Any person who processes a chemical substance or mixture. To process means to prepare a chemical substance or mixture, after its manufacture, for distribution in commerce in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or as part of a mixture or article containing the chemical substance or mixture.

4.2 ChemView Instructions

The EPA ChemView website https://java.epa.gov/chemview has links to a ChemView User's Guide on the User's Guide and Web Service Information. The User's Guide includes

- Selecting chemical search criteria
- Selecting outputs
- Generating results
- Viewing results
- Appendix of specific sources.

The Web Services URLs (uniform resource locators) site describes dropdowns for the user to select the chemicals, SNUR uses, uses, groups, categories, and endpoints. The site also enables the user to select different sources to get the chemical results. The default output format is JavaScript Object Notation (JSON). ChemView also provides the ability to download to Excel, XML, and PDF.⁵¹

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⁵⁰ ChemView Public UI [User Interface] Guide Release 1.3, U.S. Environmental Protection Agency, October 2015, 42 pages. Available at: https://java.epa.gov/chemview/resources/ChemView%20Public%20UI%20Guide.pdf.

⁵¹ ChemView Web Services URLs. Release 1.1, U.S. Environmental Protection Agency, February 19, 2014. Available at https://java.epa.gov/chemview/resources/ChemView WebServices.pdf.



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